



H.R. 1, the Medicare Prescription Drug and Modernization Act of 2003

(Major changes from the Ways and Means reported bill are in italics)

Prescription Drug Benefit – Part D

- Drug benefit under new Part D begins Jan. 1, 2006. Standard benefit:
 - \$250 deductible (increases by inflation each year based on Medicare drug expenditures)
 - 80/20 cost sharing (government/beneficiary) for drug costs up to \$2000 (also increases by inflation each year)
 - Catastrophic benefit begins with out-of-pocket costs of \$3500 (higher for seniors with incomes over \$60,000, increases each year for inflation).
- Average premium monthly estimated at \$35.
- Prescription drug plans (PDP) can differ from the standard benefit if providing actuarially equivalent coverage.
- Sponsors enter into a contract with the Medicare Benefits Administrator to provide PDP after submitting a bid that includes coverage provided, actuarial value, and premium amount. The Administrator designates at least 10 plan “service areas” (regions) in the country. Two plans must be available in each region. To ensure access to two plans, the Administrator may partially underwrite the risk for a plan sponsor to expand the service area of an existing plan (only restriction is that the Administrator cannot fully underwrite the plan so in theory, the Administrator could underwrite 99.9% of the risk for a plan).
- PDPs must provide access to negotiated drug prices and discounts and must disclose to the Secretary how these discounts are passed on to enrollees. A drug card is used to access the benefits (see Drug Discount Card below).
- Any willing pharmacy provider can participate. Plans may reduce co-pays for in-network pharmacies. Plans must have “sufficient” non-mail order pharmacies and “convenient access” to pharmacies (within 2 miles of most beneficiaries in urban areas, within 5 miles of most beneficiaries in suburban areas, and within 15 miles of most beneficiaries in rural areas). Beneficiaries would pay any difference in cost between mail order and a community pharmacy.
- Plans must have cost and utilization management program (including incentives to use generics), quality assurance measures, and systems to reduce errors (including an electronic prescription program).
- Plans could have tiered cost-sharing in a plan with a formulary and provide lower cost-sharing for “preferred drugs.”
- Low-income subsidies:

- Below 135% of poverty – 100% premium subsidy, reduced cost-sharing of (at the most) \$2 for multiple source or generic drugs and \$5 for non-preferred drug.
- Between 135% and 150% of poverty – income-related premium subsidy on a sliding scale from 100% subsidy to zero.
- Cost-sharing for drugs is reduced to \$2 for a multiple source or generic drug and \$5 for a non-preferred drug.
- Premium subsidies for all beneficiaries equal to 73%. Subsidy is paid to the plan sponsor through a combination of direct subsidy (equal to 43% of the national average monthly bid amount) and reinsurance (equal to 30% of the total payments made for standard drug coverage).
- Subsidies for employers who maintain employer-based coverage for retirees equal to 28% of drug costs, but not to exceed \$5,000 annually for an individual. Employer-based coverage must provide at least the same coverage as the standard drug benefit.
- Medicare is primary payer for drugs, including for those seniors also eligible for Medicaid. Federal assumption of the costs of premiums and cost-sharing subsidies for dual eligibles (individuals eligible for both Medicaid and Medicare), currently paid through state Medicaid programs, would be phased in.
- Enrollees in a Medicare Advantage or Enhanced Fee For Service drug plan may only receive drug coverage through that plan.
- After January 1, 2006, no new MediGap policies may cover prescription drugs unless replacing an old policy that covers drugs.

Drug Discount Card

- Administrator endorses drug card programs that provide discounts.
- Transition program only until Part D benefits are available in 2006.
- Requirements of card plans:
 - Must pass discounts to beneficiaries
 - Cannot apply only to mail order pharmacies
 - Must provide support services and information to beneficiaries
 - Must have demonstrated experience, quality assurance procedures, and confidentiality protections
 - Must have an enrollment fee of \$30 or less
- *The card would work somewhat like a debit card, with deposits onto the card made by the federal government for low-income beneficiaries:*
 - *135% of poverty or below: deposit of \$800*
 - *135%-150% of poverty: deposit of \$500*
 - *Over 150% of poverty: deposit of \$100*
- *Employers and individuals could contribute to a drug card account, but total annual deposits could not exceed \$5000.*
- Appropriates \$2 billion in 2003 and \$3 billion in 2004 for low-income assistance through the drug card (those under 150% of poverty).
- Authorizes “such sums” for the Administrator to oversee the programs.

Provisions Related to Drug Costs

- *Makes changes to ensure faster approval of abbreviated drug applications for generic drugs.*
- *Makes changes related to patent extension through the Food and Drug Administration, including giving drug manufacturers only one opportunity to appeal the expiration of a brand-name patent and extend the patent for 30 months.*
- *Requires the Secretary to develop regulations that allow for the importation of drug from Canada into the U.S provided that the Secretary “demonstrates to the Congress that the implementation of this section will pose no additional risk to the public’s health and safety” and will result in a significant reduction in the cost of prescription drugs to the consumer. The regulations must include the following requirements:*
 - *the drug must comply with FDA requirements, including provisions regarding safety and effectiveness.*
 - *the importer of the drug must comply with FDA requirements, including requirements that the importer provide documentation to the Secretary on the date the drug was shipped and in what quantity, certification that the drug is approved for use in the U.S., and laboratory records. The foreign seller must also provide a variety of documentation, including the original source of the drug and the quantity of drugs received.*
 - *the foreign seller must register with the Secretary.*
 - *importation on a drug would suspend “on discovery of a pattern of importation of that specific prescription drug or by that specific importer of drugs that are counterfeit or in violation of any requirement under this section, until an investigation is completed and the Secretary determines that the public is adequately protected from counterfeit and violative prescription drugs being imported.”*

Medicare Advantage (MA) – Part C

- New Part C includes Medicare + Choice and Medicare MSAs.
- Payments equalized with FFS in 2004. After 2004, payments are increased annually by 2% or by the percentage growth in Medicare per capita costs, whichever is greater.
- Beginning in 2006, organizations submit bids against a benchmark each year based on average costs for a typical enrollee. The Medicare Benefits Administrator may reject bids or negotiates with plans.
- Plan sponsor receives drug subsidy payments and reimbursement for low-income premium and cost-sharing subsidies.
- Plans must provide the same premium for all enrollees.
- Enrollees choosing a plan with costs below the benchmark would get 75% of the savings. Enrollees choosing a plan with costs above the benchmark would pay the excess costs.
- Makes the Medicare MSA demo permanent and eliminates the cap on participation.

Enhanced Fee For Service (FFS) – Part E

- Begins January 1, 2006.
- The Administrator designates at least 10 regions as EFS regions.
- Fee for Service (FFS) or Preferred Provider Organization (PPO) plans qualify, with up to 3 EFS plans in any region.
- Organizations submit bids against a benchmark each year based on average costs for a typical enrollee in the region. The Administrator may reject bids or negotiate with organizations.
- Enrollees choosing a plan with costs below the benchmark would get 75% of the savings. Enrollees choosing a plan with costs above the benchmark would pay the excess costs.
- Plans must be offered to all eligible individuals in the region and must provide services equal to Part B.
- Plans must provide the same premium and cost-sharing charges throughout the region.
- Plan sponsor receives drug subsidy payments and reimbursement for low-income premium and cost-sharing subsidies.

Medicare Competition in 2010

- Establishes competitive EFS regions in areas where at least 2, but no more than three, EFS plans were offered during the previous year in addition to traditional FFS Medicare. A certain percentage (20 percent or the national percentage of eligible individuals enrolled in EFS and Medicare Advantage, whichever is less) of EFS eligible individuals in the area must be enrolled in an EFS plan before it can be designated as competitive EFS.
- Establishes competitive MA regions in areas where at least 2 MA plans were offered during the previous year in addition to traditional FFS Medicare. A certain percentage (20 percent or the national percentage of eligible individuals enrolled in EFS and Medicare Advantage, whichever is less) of MA eligible individuals in the area must be enrolled in an MA plan before it can be designated as competitive MA.
- Different sponsors must offer the plans in each region.
- Plans submit bids for covering standard Medicare benefits, including prescription drugs. (Note: This is similar to competitive bidding, unlike FEHBP where any plan may offer coverage, regardless of cost, if it meets minimum criteria).
- Enrollees choosing a plan bidding below the benchmark payment rate (weighted average of all bids) would get 75% of the savings. Enrollees choosing a plan with costs above the benchmark would pay the excess costs. New benchmark is phased in over five years and during that period traditional FFS premium increases would be limited.

Waste, Fraud, and Abuse Provisions

- Sets up “competitive acquisition areas” designated by the Secretary.
- Competitive bidding for durable medical equipment, medical supplies, other equipment and supplies, and off-the-shelf orthotics phased in over three years.

- Competitive bidding for outpatient drugs and biologicals in Part A (oncology beginning in '05, and non-oncology beginning '06). The Secretary awards contracts to at least 2 providers in competitive acquisition areas.
- Three year demo program in 2 states (those with highest utilization rates) using recovery audit contractors to identify underpayments and overpayments and recoup overpayments.

Rural Health Package (\$27.2 billion based on preliminary CBO estimates)

- Disproportionate Share (DSH) formula for large urban hospitals applied to other hospitals, with a maximum adjustment of 10% (except for rural referral centers).
- Equalizes the standardized amount under the inpatient PPS for rural and urban hospitals.
- New essential rural hospital classification as part of the Critical Access Hospital program (high percentage of Medicare patients, adverse effect if closed).
- Critical Access Hospitals – payments based on 102% of costs.
- Two-year extension of the outpatient PPS hold harmless for small rural hospitals and sole community hospitals.
- Excludes certain rural health clinics and federally qualified health center services from Skilled Nursing Facility PPS.
- 5% home health payment increase for 2004 and 2005.
- 5% increase in ambulance payments.
- 5% physician payment bonus in areas with few primary physicians or specialists beginning in 2004.

Provider Payment Adjustments – Part A and Part B

- Inpatient services payment for 2004-2006 of market basket minus 0.4% points. 2007 and beyond payment equals market basket.
- Home health payment for 2004-2006 of market basket minus 0.4% points.
- Provides coverage of hospice consultation services under Part A.
- Update of the single conversion factor for physicians in 2004 and 2005 of not less than 1.5% (instead of currently scheduled 4.2% reduction for 2004).
- Coverage under Part B for a beneficiary's initial physical and cholesterol and blood lipid screening once every two years. Waiver of Part B deductible for colorectal cancer screening tests.
- Outpatient drug payment for 2004-2006 cannot exceed 95% of the average wholesale price (AWP) or transition percentage (83-71% for sole source drugs, 81.5%-68% for multisource drugs, 46% for generic drugs). After 2006, payment would be equal to the average price of the drug in the area as determined under the competitive acquisition program. This would replace AWP. An exception is made for oncology drugs, which would be reimbursed at the "average sale price" and an addition 12% payment.
- One-year moratorium on the \$1500 outpatient therapy cap.
- After 2003, the Part B deductible increases annually for inflation (based on overall Part B spending, the same process by which premiums are currently increased).

- New home health co-payment equal to 1.5% of the national average payment per episode of care (no more than \$40). Co-pay reduced for low-income beneficiaries or those with four or fewer visits.
- New Chronic Care Improvement program. The Secretary awards contracts for programs in regions (also determined by the Secretary) to provide chronic care services to beneficiaries not enrolled in Part C (Medicare Advantage) or Part E (FFFS). Authorizes “such sums,” but not more than \$100 million over three years, for administration of the program. MA and FFS plans must also have chronic care improvement components.

Medicare Benefits Administration

- Sets up new MBA within HHS.
- Headed by Medicare Benefits Administrator appointed by the President and approved by the Senate for a 4-year term.
- Oversees Part C (Medicare Advantage), Part D (drug benefit), and Part E (FFFS).
- Within the MBA new offices of Beneficiary Assistance and Medicare Policy Advisory Board.

Regulatory Reforms

- No retroactive application of substantive changes.
- Allows the Secretary to contract with “Medicare administrative contractors) for certain functions like making payments, beneficiary assistance, consultation services, and provider education.
- \$25 million in 2005 and 2006 (such sums thereafter) for provider education.
- \$1 million in 2005 and 2006 for small provider technical assistance demo.
- Requires the Secretary to appoint a Medicare Provider Ombudsman and Medicare Beneficiary Ombudsman.
- Beneficiary outreach demo through Social Security Agency offices.
- Transfers Medicare appeals from SSA to HHS.
- Establishes process for expedited judicial review for providers.
- The Secretary can enter into repayment plans with providers if returning an overpayment is a hardship.
- Establishes an overutilization process for the Secretary to provide notice to providers if certain billing codes are being overutilized.
- Establishes a process for providers to correct minor claims errors.

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